California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person
Virginia Herold
(916) 574-7911

LEGISLATION AND REGULATION COMMITTEE
January 8, 2007, 9:30 a.m.
Department of Consumer Affairs Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting the board's office at (916) 574-7900, at least five working days prior to the meeting.

Opportunities are provided to the public to address the committee on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

Times are approximate and are subject to change

A. Call to Order 9:30 a.m.

B. Approved Regulations
1. Amend CCR 1793.7 and add CCR 1793.8 – Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Setting
2. Repeal CCR 1717(e) and add CCR 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

C. Board Adopted Regulations– Pending Administrative Review
1. Proposed Repeal of 16 CCR 1717.2 – Notice of Electronic Prescription Files
2. Proposed Adoption of 16 CCR 1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge

D. Boarded Approved Regulations Currently Noticed – Action Recommended at January 2007 Board Meeting
1. Proposed Amendment of 16 CCR 1706.2 – Abandonment of Application Files
2. Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation

E. Board Approved Regulations Awaiting Notice
1. Section 100 Changes
    - Proposed Amendment to CCR 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"

- Proposed Amendment to CCR 1780 – Update the USP Standards Reference Material
- Proposed Amendment to CCR 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"
- Proposed Repeal of CCR 1786 – Return of Exemption Certificates

2. Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines

F. Board Approved Regulation Awaiting Conformance with California Building Standards Rulemaking Process

Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parental Solutions; Technical Changes to the Building Code Relating to Pharmacies

G. Board Approved Regulations – Proposed Language to be Developed

1. Proposed Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies.
2. Notice to Consumers – Currently under review by the Public Education Committee for refinement.

H. Requests for Legislation and Regulatory Proposals for 2007

1. Proposed Legislation

a. Ominbus Provisions
   - Adulterated or Counterfeit Drugs or Dangerous Devices – B&PC section 4084
   - Wholesaler: Bonding Requirements – B&PC sections 4162 and 4162.5
   - Citation and Fine for Repository and Distribution Programs for Dangerous Drugs – B&PC sections 4314 and 4315
   - Temporary License Fees for Wholesalers - B&PC section 4160(f) and 4161(k)
   - Intern Pharmacist License - B&PC section 4208
   - Voiding of License When Licensed Premises Remains Closed – B&PC 4312

b. Proposed changes to AB 2986 Chaptered 2006.
c. Licensing of Headquarters for Chain Pharmacies

2. Proposed Regulations

a. Section 100 Changes
   - Self Assessment Forms – 16 CCR 1715

b. Proposed Addition to 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

I. Public Requests for Future Legislation and Regulatory Proposals

The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problem.

J. New Business

Adjournment

Committee materials will be available on the board's Web site by January 3, 2007.

Agenda Item B

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Approved Regulations

The Office of Administrative Law recently approved two board rulemaking files.

Amend 16 CCR 1793.7 and add 16 CCR 1798.8 – Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Setting
Section 1793.7 was amended and Section 1798.8 was added to Title 16 to define the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting. This regulation takes effect January 5, 2007.

Repeal 16 CCR 1717(e) and add 16 CCR 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions
Section 1717(e) was repealed and Section 1713 was added to Title 16 to allow pharmacy patients the ability to use a vending-like machine located near the pharmacy to obtain their refill medication if they choose to do so. This regulation also allows the use of a prescription drop-off box outside the pharmacy as a means to leave a prescription for a pharmacy to later fill. These changes are effective January 26, 2007

Copies of the exact language are provided.

Board of Pharmacy
Specific Language

Amend Section 1793.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Adopt Section 1793.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.
Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code.
Reference cited: Sections 4007, 4038, 4115 and 4202, Business and Professions Code.

Board of Pharmacy
California Code of Regulations
Change to Title 16, Division 17

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.
(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.
(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.
(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.
(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and

the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Agenda Item C

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Adopted Regulations - Pending Administrative Review

At the October 2006 board meeting, the board voted to adopt two pending regulation changes.

Repeal of 16 CCR 1717.2 Notice of Electronic Prescription Files
The repeal of Section 1717.2 of the California Code of Regulations removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy. This rulemaking was submitted to the Department on November 1, 2006.

Adoption of 16 CCR 1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge
The adoption of Section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This rulemaking was submitted to the Department on December 28, 2006.

Copies of the exact language are provided.

Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1717.2. Notice of Electronic Prescription Files.**~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~_____ _____~~
~~(date) (signature of patient)~~

~~_____~~
~~_____ (acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

Board of Pharmacy
California Code of Regulations
Specific Language to Add Section 1784, Division 17

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new wholesaler permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.
(c) The components of this assessment shall be on Form 17M-26 (rev. ~~8~~12/14/2006) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

Virginia Herold, Interim Executive Officer _____ Date

Agenda Item D

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Currently Noticed – Action Recommended at the January 2007 Board Meeting.

The following pending regulations were noticed on December 22, 2006. The Comment period is over February 5, 2007, however the board may take action on the two pending regulations at the January Board meeting, even though the 45-day period has not run, as long as a motion is made to adopt the regulations as noticed and absent any negative comments or substantive changes.

Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation.

Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation.

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

Copies of the Notice, language and Initial Statement of Reasons are provided.

Section 1706.2

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 5, 2007.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on January 22, 2006.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 4005 and to implement, interpret, and make specific reference to sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to complete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action other states other than the forfeit of an application fee submitted for an application that is deemed abandoned.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business other than the forfeit of an application fee submitted for an application that is deemed abandoned

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Abandonment of Application Files

Sections Affected: Amend 1706.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes amending Section 1706.2 of the California Code of Regulations to add applicants for veterinary food-animal drug retailers, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation.

Discussion: In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy and sterile injectable compounding pharmacy to the regulation and delete the terms manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change will add applications for licenses to operate veterinary food-animal drug retailers, sale or dispense hypodermic needles and syringes, serve as a pharmacist intern or designated representative to the regulation.

Factual Basis/Rationale

Currently there is no provision in pharmacy law that defines when an application for a license to operate a veterinary food-animal drug retailer, sale or dispense hypodermic needles and syringes, serve as a pharmacist intern or designated representative. This proposal will make consistent the conditions under which these applications may be abandoned.

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Board of Pharmacy
Specific Language

Amend Section 1706.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy~~,~~ wholesaler, out-of-state distributor, ~~or~~ clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.
(e) An applicant for a pharmacist intern license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code.

Section 1775.4

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 5, 2007.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on January 22, 2007.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 125.9, 148, 685 and 4005 of the Business and Professions Code and Section 56.63 of the Civil Code, and to implement, interpret or make specific Sections 125.9, 148 and 685 of the Business and Professions Code and Section 56.63 of the Civil Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to $5,000 for violations of the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the regulations adopted pursuant thereto.

Business and Professions Code Section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to $5,000 to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice).

Business and Professions Code Section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code Section 4005 authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code Section 4067 authorizes the board to issue a citation with a fine of up to $25,000 per violation for dispensing a dangerous drug or dangerous

device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code Section 4127.4 authorizes the board to issue a citation with a fine of up to $2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code Section 56.36 authorizes the board to issue citations and fines ranging from $5,000 up to $250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

Section 1775.4 details the procedures for contesting a citation. This proposal would allow for a person or entity to request that the informal office conference to contest a citation issued be rescheduled. Such a request could only be made once.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:
The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not affect small businesses. The proposed regulations affect internal board operations and would have no effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy determined that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Citation and Fine Appeals

Sections Affected: Repeal Amend 1775.4

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

Factual Basis/Rationale

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to $5,000 for violations of the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the regulations adopted pursuant thereto.

Business and Professions Code section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to $5,000 to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice).

Business and Professions Code section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code section 4067 authorizes the board to issue a citation with a fine of up to $25,000 per violation for dispensing a dangerous drug or dangerous device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code section 4127.4 authorizes the board to issue a citation with a fine of up to $2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code section 56.36 authorizes the board to issue citations and fines ranging from $5,000 up to $250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

Section 1774.5 of the California Code of Regulations allows a person or entity served with a citation to contest the citation. Such individuals can either request a hearing before an administrative law judge pursuant to the Administrative Procedures Act, request an informal office conference conducted by the board's executive officer or his or her designee, or both. This section details many of the procedures for the informal office conference, including necessary timeframes, but does not allow for an office conference to be rescheduled. This proposal would allow for a person or entity to reschedule the office conference one time.

Underlying Data

The board issued 774 citations in FY 2005/2006.
The board scheduled 177 informal office conferences during FY 2005/2006, 48 individuals requested to postpone the appeal conference and an additional seven persons or entities failed to appear at the scheduled office conference.

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to repealing the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the repeal of the regulation.

Board of Pharmacy
Specific Language

Amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1775.4 (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)
(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference, The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once by submitting a written request at least 2 days in advance of the scheduled office conference.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Note: Authority cited: Sections 129.5, 148 and 4005, Business and Professions Code. Reference: Sections 125.9, 148, 684, 4067, 4127.4 and Business and Professions Code and Section 56.36 of the Civil Code.

Agenda Item E

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

The board previously approved four Section 100 changes. (A Section 100 change is used when a regulation requires changes that are technical rather than substantive.) These proposals are pending.

Proposed Amendment to 16 CCR 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"
In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material
Section 1780 sets minimum standards for drug Wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

Proposed Amendment to 16 CCR 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"
In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006.
Copies of the Notice, language and Initial Statement of Reasons are provided. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Repeal of 16 CCR 1786 – Return of Exemption Certificates
This section is outdated and needs to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leave the employment of a wholesaler. This regulation is based on prior Pharmacy Law which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines
In addition to the Section 100 changes listed above, the board also approved amendment to 16 CCR 1760 – Disciplinary Guidelines.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff has additional recommendations for changes that will be presented to the board at the April 2007 board meeting. No action will be taken on this proposal pending the outcome of the April 2007 board meeting.

Board of Pharmacy
Specific Language

CCR 1709.1 Designation of Pharmacist-in-Charge

Amend Section 1709.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

CCR 1780. Minimum Standards for Wholesalers.

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:
(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair.

Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990~~ 2005, 28th ~~22nd~~ Revision).

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990~~ 2005, 28th ~~22nd~~ Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

CCR 1780.1.Minimum Standards for Veterinary Food-Animal Drug Retailers

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.
a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.
b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.
e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.
f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.
g. Refilling A Veterinarian's Prescription
(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.
(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.
h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:
(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer

(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)

(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the qualifying

experience earned by an applicant for registration must do so under penalty of perjury.

Note: Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

CCR 1781. Exemption Certificate

Amend Section 1781 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

A registered pharmacist, or ~~an exemptee~~ designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.

CCR 1786. Exemptions.

Repeal Section 1786 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~(a) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4054, leaves the employ of a supplier, said supplier shall immediately return the certificate of exemption to the board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4051, 4053 and 4054, Business and Professions Code.~~

Agenda Item F

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Conformance with California Building Standards Rulemaking Process

At the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. This summer, the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. Staff will pursue these changes in the new format this year to secure adoption of these standards into the building code.

Agenda Item G

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations – Proposed Language to be Developed

Process and Criteria to Approve Accreditation Agencies for Pharmacies

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Language will be developed in concert with staff counsel and will be presented at the next Legislation and Regulation Committee meeting.

Notice to Consumers

In conformance with AB 2583 (Chapter 487, Statutes of 2006) the board is required to revise the Notice to Consumers poster developed and provided to each pharmacy as required in Business and Professions Code section 4122 and defined in 16 CCR 1707.2. This proposal is being refined by the Public Education and Outreach Committee and a final version will be presented to the board at the January 2007 Board Meeting.

Agenda Item H (1)

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Proposed Legislation for 2007:

Omnibus Provisions

All of the following provisions should be omnibus provisions for 2007. Copies of the exact language follow.

- **Sections 4162 and 4162.5**
  Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.
- **Sections 4314 and 4315**
  Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.
- **Section 4084**
  To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
- **Sections 4160(f) – 4161(k)**
  Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.
- **Section 4208**
  Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.
- **Section 4312**
  Suggested revisions will be provided at the January 8, 2007, meeting. The language provided with this packet is the current law. The suggested changes are recommended to alleviate some of the administrative burden placed on licensees.

Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)

The above legislation changes the reporting requirement for CURES, expands reporting to include Schedule IV controlled substances and adds elements that must be entered into CURES (e.g., the patient phone number and number of refills). Specifically, C-IIs,

IIIs, and IVs now must be submitted weekly to Atlantic Associates. The board will monitor compliance with this requirement during 2007 inspections and is encouraging pharmacies to work with their software vendors to ensure compliance ASAP.

However, staff is also recommending a specific amendment to mandate a January 1, 2008, "drop dead date" for aggressive enforcement, as well as a requirement for prescribers to use of the new security prescription forms that contain the new data fields, also by January 1, 2008 (essentially by making the current security forms obsolete).

A draft of the proposed revisions is included.

Licensing of Headquarters for Chain Pharmacies

Staff is recommending that the board consider the possibility of issuing a headquarters license to chain pharmacies. This will formally establish a process already used by the board and will also provide the board with the latitude to pursue action against a headquarters when appropriate (instead of a specific site.)

Board of Pharmacy
2007 Omnibus Bill Proposed Language

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device

Amend Section 4084 of the Business and Professions Code, to read:

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.
(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
(f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

B&P 4162 & 4162.5 Wholesaler License Surety Bond Requirements

Amend Sections 4162 and 4162.5 of the Business and Professions Code to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).
(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).
(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one

hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, ~~2011~~ 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, ~~2011~~ 2015, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to

this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

B&P 4160 Wholesaler License Required

Amend Section 4160 & 4161 of the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler~~. A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(g) This section shall become operative on January 1, 2006.

4161 a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.~~ A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

B&P 4208 Intern Pharmacist License

Amend Section 4208 of the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.
(c) An intern pharmacist shall notify the board within 30 days of any change of address.
(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) Persons who have not completed experience requirements necessary to be eligible for the licensure examination may have their intern license extended for a period of up to two years at the discretion of the board if able to demonstrate their inability to exercise the privileges of the intern license during the initial license period.

B&P 4312 Voiding License of Entity Remaining Closed

Amend Sections 4312 of the Business and Professions Code, to read:

4312. (a) The board may cancel the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.
(b) In the event that the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.
(c) If a wholesaler, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, pharmacy, or veterinary foodanimal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, or veterinary food-animal drug retailer.
(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.
(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Board of Pharmacy
Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)

CURES REPORTING

SECTION 1. Section 11162.1 of the Health and Safety Code is amended to read:
11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:
(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
(3) A chemical void protection that prevents alteration by chemical washing.
(4) A feature printed in thermo-chromic ink.
(5) An area of opaque writing so that the writing disappears if the prescription is lightened.
(6) A description of the security features included on each prescription form.
(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:
1–24
25–49
50–74
75–100
101–150
151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.
(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
(11) The date ~~of origin of~~ the prescription <u>was written/ordered for the patient by the prescriber.</u>
(12) A check box indicating the prescriber's order not to substitute.
(13) An identifying number assigned to the approved security printer by the Department of Justice.
(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.
(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility, the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons preprinted on the form.
(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and be maintained in the health facility for three years.
(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
~~(d) This section shall become operative on July 1, 2004.~~

SEC. 2. Section 11164 of the Health and Safety Code is amended to read:
11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the patient's name ~~of the ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription ~~is a~~ is being filled initially or as ~~first-time request or~~ a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:
11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.
(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.
(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy shall provide the following information to the

Department of Justice on a weekly basis each Monday for the preceeding week (Monday through Sunday), and in a format specified by the Department of Justice:
(1) Full name~~,~~ and address~~, and the telephone number~~ of the ~~ultimate user~~ patient or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered.
(8) Whether the drug was dispensed initially from a prescription or as a refill ~~of a prescription or as a first-time request~~.
(9) Date of origin of the prescription.
(10) Date of dispensing of the prescription.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:
11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 5. Section 11190 of the Health and Safety Code is amended to read:
11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, and the telephone number of the patient ~~ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Number of refills ordered.
(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
(H) Date ~~of origin of~~ the prescription was ordered for the patient by the prescriber.
(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.
(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user.
~~(d) This section shall become operative on January 1, 2005.~~
(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.
(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Agenda Item H (2)

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Proposed Regulations

Section 100 Changes

Board staff is recommending to the board two additional Section 100 changes for board consideration.

Amendment to 16 CCR 1715 – Self-Assessment Form
This regulation establishes by reference the self-assessment form used by the pharmacist-in-charge to confirm compliance with pharmacy law at a licensed pharmacy. As pharmacy law changes, this form needs to be revised to reflect such changes. It is time to update the form again to make it current with 2007 law

Amendment to 16 CCR 1793.8 – Pharmacy Technicians in Hospitals.
This regulation defines the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting. This section currently references Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

Addition of 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer.
The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

Board of Pharmacy
2007 Proposed Section 100 Language

Amend Section 1715 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.
(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new pharmacy permit has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
(c) The components of this assessment shall be on Form 17M-13 (Rev ~~1/05~~ 3/07) entitled "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev ~~1/05~~ 3/07) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4305, 4330, 4332 and 4333, Business and Professions Code.

Amend Section 1793.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in ~~4052~~ 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Section 4005 and 4115, Business and Professions Code.
Reference: Section 4005 and 4115 Business and Professions Code.

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-?? (rev. ??/??/2007) entitled "Veterinary Food-Animal Drug Retailer of Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.